

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

MARYSUSAN CATHOLDI-JANKOWSKI,
individually and on behalf of all others
similarly situated,

Plaintiff,

v.

CVS HEALTH CORPORATION, *a Rhode*
Island Corporation, and CVS PHARMACY,
INC., *a Rhode Island Corporation*,

Defendants.

DECISION AND ORDER

6:22-CV-06227 EAW

INTRODUCTION

Plaintiff Marysusan Catholdi-Jankowski (“Plaintiff”) brings this putative class action against defendants CVS Health Corporation (“CVS Health Corp.”) and CVS Pharmacy, Inc. (“CVS Pharmacy”) (collectively “Defendants”), alleging violations of the New York General Business Law as well as common law claims of fraud and unjust enrichment. (Dkt. 1). Presently before the Court are Defendants’ respective motions to dismiss the complaint. (Dkt. 7; Dkt. 8). For the reasons that follow, the Court grants Defendants’ motions to dismiss, and conditionally grants Plaintiff’s request to file an amended complaint.

FACTUAL BACKGROUND

Plaintiff alleges that Defendants “sell at their stores and elsewhere” CVS-brand alcohol-based hand sanitizer. (Dkt. 1 at ¶ 2). According to Plaintiff, the bottles in which

CVS-brand hand sanitizer is packaged contain statements that the product kills 99.99% of germs. (*Id.*). In addition, “[t]he front label of each bottle of Defendant’s [sic] hand sanitizer contains an asterisk, which leads to the statement on the back label, in miniscule font, that reads: ‘In as little as 15 seconds, kills more than 99.99% of many common germs that may cause illness.’” (*Id.* at ¶ 6). Plaintiff takes the position that these statements, “in that they are made with a degree of certainty to the hundredth digit, necessarily imply that a scientific study proves that the product in fact kills 99.99% of germs.” (*Id.* at ¶ 3).

However, “it is scientifically proven that alcohol-based hand-sanitizer does not kill many types of germs,” including non-enveloped viruses such as the norovirus, bacterial spores, protozoan cysts, certain parasites (including Giardia), and “the diarrhea-causing bacterium *Clostridium difficile*.” (*Id.* at ¶ 4). This means, according to Plaintiff, that “no scientific study can prove with any degree of certainty the overall percentage of germs which alcohol-based hand-sanitizer kills.” (*Id.*). Plaintiff further elaborates that, “[t]here is estimated to be somewhere between 100 billion and 1 trillion different microbial species on earth. The current catalogued species of microbes accounts for approximately 0.001% of germs in existence. In other words, 99.999% of germs are yet to be discovered and identified.” (*Id.* at ¶ 8).

Plaintiff claims to have purchased CVS-brand alcohol-based sanitizer, the label of which “stated prominently that the product . . . ‘kills 99.99% of germs.’” (*Id.* at ¶ 16). This statement contained an asterisk, leading to a statement on the back label that read: “In as little as 15 seconds, kills more than 99.99% of many common germs that may cause illness.” (*Id.* at ¶ 17). Plaintiff did not read the statement included on the back label, but

did read the statement on the front of the label, and believed that it “meant that it was scientifically proven that the hand-sanitizer would kill 99.99% of all known germs.” (*Id.* at ¶ 18). Plaintiff asserts that she “purchased the hand-sanitizer in reliance on the representation, believing that it had in fact been scientifically proven that the hand-sanitizer killed 99.99% of all germs.” (*Id.* at ¶ 25). Plaintiff further claims to have paid a “price premium” based on this understanding and her belief that the CVS-brand hand sanitizer was more effective at killing germs than competitors’ brands that did not have similar statements. (*Id.* at ¶¶ 26-31). Plaintiff further alleges that she “continues to desire to purchase hand sanitizer which will actually kill 99.99% of germs” and that she “would purchase Defendant’s [sic] hand sanitizer again if Defendant [sic] reformulates its hand sanitizers to actually kill 99.99% of germs.” (*Id.* at ¶ 33).

PROCEDURAL BACKGROUND

Plaintiff filed the complaint on May 18, 2022. (Dkt. 1). Defendants filed the instant motions to dismiss on June 16, 2022. (Dkt. 7; Dkt. 8). Plaintiff filed her response on July 7, 2022. (Dkt. 16; Dkt. 17). CVS Pharmacy filed a reply on July 14, 2022. (Dkt. 19). The Court held oral argument on February 13, 2023, and reserved decision. (Dkt. 22).

DISCUSSION

I. CVS Health Corp.’s Motion to Dismiss

CVS Health Corp. seeks dismissal of the claims against it on multiple grounds. It notes that it has been named as “CVS Health Corporation, a Rhode Island Corporation,” but that “[t]here is no Rhode Island Corporation by the name of CVS Health Corporation,” inasmuch as it is incorporated in Delaware. (Dkt. 7-2 at 5). It further notes that it “neither

manufactured, distributed, nor sold the hand sanitizer Product at issue,” and asserts that the Court lacks personal jurisdiction over it. (*Id.*). It additionally argues that “the Complaint should be dismissed under Fed. P. Civ. R. 8, 12(b)(1) and (6) because Plaintiff impermissibly lumps CVS Health and CVS Pharmacy together, and she makes no specific allegations as to CVS Health.” (*Id.*).

In her response, Plaintiff states that she “does not oppose Defendant CVS Health Corporation’s . . . motion to dismiss.” (Dkt. 16 at 11 n.1). At oral argument, Plaintiff’s counsel confirmed that Plaintiff consented to the dismissal of the claims against CVS Health Corp. on the merits and with prejudice. Without objection by Plaintiff, the Court grants CVS Health Corp.’s request for dismissal with prejudice.

II. CVS Pharmacy’s Motion to Dismiss

CVS Pharmacy seeks dismissal pursuant to Federal Rule of Civil Procedure 12(b)(1) on the basis that Plaintiff lacks standing, as well as pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. “When the issue before the Court involves a motion to dismiss pursuant to Rules 12(b)(1) and 12(b)(6), the Court must consider the Rule 12(b)(1) motion first, because disposition of a Rule 12(b)(6) motion is a decision on the merits, and therefore, an exercise of jurisdiction.” *Gonzalez v. Inn on the Hudson LLC*, No. 20 CIV. 9196 (ER), 2022 WL 974384, at *2 (S.D.N.Y. Mar. 30, 2022) (citations and quotation omitted). The Court accordingly turns first to CVS Pharmacy’s arguments made under Rule 12(b)(1).

A. Legal Standard—Rule 12(b)(1)

“A district court properly dismisses an action under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction if the court lacks the statutory or constitutional power to adjudicate it, such as when . . . the plaintiff lacks constitutional standing to bring the action.” *Cortlandt St. Recovery Corp. v. Hellas Telecomms, S.á.r.l.*, 790 F.3d 411, 416-17 (2d Cir. 2015) (quotation and citation omitted). “A plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists.” *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). “When considering a motion to dismiss for lack of subject matter jurisdiction . . ., a court must accept as true all material factual allegations in the complaint.” *Shipping Fin. Servs. Corp. v. Drakos*, 140 F.3d 129, 131 (2d Cir. 1998). In addition, a court is not limited to the allegations in the complaint and can “refer to evidence outside the pleadings,” *Luckett v. Bure*, 290 F.3d 493, 496-97 (2d Cir. 2002), but it “may not rely on conclusory or hearsay statements contained in the affidavits.” *J.S. v. Attica Central Schools*, 386 F.3d 107, 110 (2d Cir. 2004). “Indeed, a challenge to the jurisdictional elements of a plaintiff’s claim allows the Court to weigh the evidence and satisfy itself as to the existence of its power to hear the case.” *Celestine v. Mt. Vernon Neighborhood Health Ctr.*, 289 F. Supp. 2d 392, 399 (S.D.N.Y. 2003) (quotation omitted), *aff’d*, 403 F.3d 76 (2d Cir. 2005).

B. Article III Standing

Like all Article III courts, this Court may only hear “cases and controversies.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559 (1992); *see also Whitmore v. Arkansas*, 495 U.S. 149, 154-55 (1990) (“Article III, of course, gives the federal courts jurisdiction over

only ‘cases and controversies. . . .’). While the Constitution does not define “case” or “controversy,” “the doctrine of standing serves to identify those disputes which are appropriately resolved through the judicial process.” *Whitmore*, 495 U.S. at 155. The Second Circuit has explained:

To satisfy the requirements of Article III standing, plaintiffs must demonstrate “(1) [an] injury-in-fact, which is a concrete and particularized harm to a legally protected interest; (2) causation in the form of a fairly traceable connection between the asserted injury-in-fact and the alleged actions of the defendant; and (3) redressability, or a non-speculative likelihood that the injury can be remedied by the requested relief.”

Hu v. City of New York, 927 F.3d 81, 89 (2d Cir. 2019) (quoting *Selevan v. New York Thruway Auth.*, 711 F.3d 253, 257 (2d Cir. 2013)).

CVS Pharmacy contends that Plaintiff lacks Article III standing as to all of her claims because she has not suffered an injury-in-fact. (Dkt. 19 at 12). More particularly, CVS Pharmacy argues that Plaintiff does not allege that the product she purchased did not actually sanitize her hands, and so “her alleged injury is not concrete and particularized and actual or imminent, not conjectural or hypothetical[.]” (*Id.* (quotations omitted)). The Court is unpersuaded by this argument.

In support of this contention, CVS Pharmacy relies heavily on two out-of-Circuit cases, *Aleisa v. GOJO Indus., Inc.*, 538 F. Supp. 3d 764 (N.D. Ohio 2021), and *Moreno v. Vi-Jon, LLC*, No. 20CV1446 JM(BGS), 2021 WL 5771229, at *4 (S.D. Cal. Dec. 6, 2021). As an initial matter, the Court notes that after the briefing in this matter was completed, the Ninth Circuit reversed the *Moreno* decision in relevant part, concluding: “[The plaintiff] adequately pleaded economic injury. He alleged that he wouldn’t have purchased or paid

as much for [the defendant's] products if he had known the truth about their effectiveness. This is sufficient for an Article III injury.” *Moreno v. Vi-Jon, LLC.*, No. 21-56370, 2022 WL 17668457, at *1 (9th Cir. Dec. 14, 2022). In other words, the ultimate resolution of the standing issue in the *Moreno* case now favors Plaintiff, as defense counsel acknowledged at oral argument.

As to *Aleisa*, the court in that case found no standing where “Plaintiffs claim[ed] they would not have purchased Purell Advanced Hand Sanitizer had Defendant not marketed it as killing over 99.99% of germs,” reasoning that, “[a]ssuming the truth of this allegation, Plaintiffs have not suffered an injury. They received fair value for what they paid. They paid for hand sanitizer. They received hand sanitizer. And they did so in an arm’s length transaction.” 538 F. Supp. 3d at 772-73. However, the *Aleisa* court acknowledged that a claim that the plaintiffs “paid too much for Defendant’s hand sanitizer based on its allegedly false claims about the product” could be sufficient to confer standing if it were factually supported. *Id.* at 773. In this case, Plaintiff has alleged that she paid a premium based on CVS Pharmacy’s allegedly false statements about the germ-killing efficacy of its hand sanitizer, and has identified a number of other, lower-priced hand sanitizers that do not make similar claims. (Dkt. 1 at ¶¶ 26-31). This is sufficient to plead an economic injury, which is in turn enough to satisfy the requirements of Article III. *See, e.g., Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 575 (S.D.N.Y. 2021) (“[A]n allegation that a plaintiff would not have purchased a product or would not have paid the same amount comfortably satisfies the injury-in-fact prong of Article III standing.”).

The Court was not persuaded by defense counsel’s contention at oral argument that the standing argument essentially converges with the merits of Plaintiff’s New York General Business Law claims. “The standing question is distinct from whether [the plaintiff] has a cause of action.” *Carver v. City of New York*, 621 F.3d 221, 226 (2d Cir. 2010) (collecting cases); *see also Harry v. Total Gas & Power N. Am., Inc.*, 889 F.3d 104, 110 (2d Cir. 2018) (“It is well established in principle that the pleading standard for constitutional standing is lower than the standard for a substantive cause of action.”); *Toretto v. Donnelley Fin. Sols., Inc.*, No. 1:20-CV-2667-GHW, 2021 WL 861138 (S.D.N.Y. Mar. 5, 2021) (“Despite this clearly established distinction, . . . litigants frequently conflate standing and merits issues.”). While the Court agrees, for the reasons discussed below, that Plaintiff has not plausibly alleged a New York General Business Law violation, that does not mean that she has not alleged a sufficient injury-in-fact to establish Article III standing.

CVS Pharmacy also argues that Plaintiff lacks standing specifically to bring a claim for prospective injunctive relief. “[S]tanding is not dispensed in gross” and “a plaintiff must demonstrate standing for each claim he [or she] seeks to press and for each form of relief that is sought.” *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 581 U.S. 433, 439 (2017) (quotations omitted). “In order to meet the constitutional minimum of standing to seek injunctive relief,” a plaintiff “cannot rely on past injury” but instead must show a likelihood that he or she will be injured in the future. *Shain v. Ellison*, 356 F.3d 211, 215 (2d Cir. 2004) (citation omitted). “There is no exception to demonstrating future injury when the

plaintiff is pursuing a class action.” *Buonasera v. Honest Co., Inc.*, 208 F. Supp. 3d 555, 564 (S.D.N.Y. 2016).

Plaintiff argues that she has standing to pursue injunctive relief in this case based on her allegations that she “would purchase [the CVS-brand] hand sanitizer again if [CVS Pharmacy] reformulates its hand sanitizers to actually kill 99.99% of germs,” but that she cannot rely on the current labeling “to determine if or when [CVS Pharmacy’s] hand sanitizers are reformulated to actually kill 99.99% of germs.” (Dkt. 1 at ¶ 33). However, as CVS Pharmacy correctly points out, Plaintiff asserts elsewhere in her complaint that it is scientifically impossible for an alcohol-based hand sanitizer such as those at issue here to actually kill 99.99% of germs. (*See id.* at ¶¶ 8 (“There is estimated to be somewhere between 100 billion and 1 trillion different microbial species on earth. The current catalogued species of microbes accounts for approximately 0.001% of germs in existence. In other words, 99.999% of germs are yet to be discovered and identified. Defendants have not tested the efficacy of their hand sanitizer against every one of the approximately 0.001% of catalogued species of germs in existence. Moreover, no amount of testing during the present time can substantiate the claim that ethanol-based hand sanitizers kill ‘99.99% of germs.’”), 19 (“No scientific study indicates that alcohol-based hand-sanitizers kill 99.99% of germs. In fact, many scientific studies show that hand-sanitizers do not kill many prominent and harmful germs, and that they are less effective than washing one’s hands.”)).

“[T]he question of whether a plaintiff seeking injunctive relief for consumer deception will be able to demonstrate standing where, as here, they allege they would buy

the products in the future if not mislabeled, is unsettled in this Circuit, and district courts examining the issue have reached divergent conclusions.” *Mancuso v. RFA Brands, LLC*, 454 F. Supp. 3d 197, 205 (W.D.N.Y. 2020) (quotation and original alterations omitted and collecting cases). “However, ‘a thorough survey of authority in the Second Circuit suggests that’ a plaintiff who alleges an intent to make future purchases of a product only if its advertising or labeling is changed has failed to sufficiently allege future injury for purposes of establishing standing to seek injunctive relief: any case holding otherwise ‘is an outlier in the Circuit’s jurisprudence.’” *Id.* (original alteration omitted and quoting *Lugones v. Pete & Gerry’s Organic, LLC*, 440 F. Supp. 3d 226, 238 (S.D.N.Y. 2020)); *see also Duchimaza v. Niagara Bottling, LLC*, No. 21 CIV. 6434 (PAE), 2022 WL 3139898, at *6 (S.D.N.Y. Aug. 5, 2022) (allegations that the plaintiff “desires to purchase water bottles from Defendant Niagara that are, in fact, 100% recyclable, but cannot rely on Defendant Niagara’s representations regarding recyclability” were not sufficient to “plead an injury-in-fact to support injunctive relief,” because they “mirror[ed] pleadings that courts in this Circuit repeatedly have held insufficient where a consumer plaintiff has sought to enjoin the further sale of a deceptively marketed product she purchased” and “[a]s these courts have held, allegations that the plaintiff would purchase a product *if* re-engineered or re-marketed does not plead a real or immediate threat of future injury” (emphasis in original)).

This Court agrees with the majority view in this Circuit, and finds the reasoning of these cases particularly persuasive in this case, where Plaintiff’s own allegations are that the product could not be reformulated to meet her standards for purchasing. In other words,

Plaintiff's allegation that she would like to purchase a reformulated hand sanitizer that killed 99.99% of germs is inherently speculative if one also credits her allegations that such a reformulation is not scientifically feasible. Accordingly, Plaintiff cannot show a likelihood of future harm because—according to her own complaint—she will know that any CVS-brand hand sanitizer product she is contemplating purchasing in the future could not possibly have been scientifically proven to kill 99.99% of all germs, as she understands that term. Plaintiff thus lacks standing to seek injunctive relief and her request for the same is dismissed without prejudice.

C. Legal Standard—Rule 12(b)(6)

The Court turns next to CVS Pharmacy's arguments made pursuant to Rule 12(b)(6). "In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010). A court should consider the motion by "accepting all factual allegations as true and drawing all reasonable inferences in favor of the plaintiff." *Trs. of Upstate N.Y. Eng'rs Pension Fund v. Ivy Asset Mgmt.*, 843 F.3d 561, 566 (2d Cir. 2016). To withstand dismissal, a claimant must set forth "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Turkmen v. Ashcroft*, 589 F.3d 542, 546 (2d Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

“While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff’s obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (internal quotations and citations omitted). “To state a plausible claim, the complaint’s ‘[f]actual allegations must be enough to raise a right to relief above the speculative level.’” *Nielsen v. AECOM Tech. Corp.*, 762 F.3d 214, 218 (2d Cir. 2014) (quoting *Twombly*, 550 U.S. at 555).

CVS Pharmacy seeks dismissal on the bases that: (1) Plaintiff’s claims are preempted by the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d, 247d-6e; (2) Plaintiff’s claims are barred by the doctrine of primary jurisdiction¹; (3) Plaintiff has not plausibly alleged that a reasonable consumer would be misled by the labeling at issue; (4) Plaintiff has not met the heightened pleading standard applicable to claims of fraud and her fraud claim is in any event barred by the economic loss doctrine; and (5) Plaintiff’s unjust enrichment claim fails because she has an adequate remedy at law. (Dkt. 8-3). As confirmed at oral argument, Plaintiff does not oppose the dismissal

¹ Courts have sometimes considered similar arguments under Rule 12(b)(1), despite the fact that Rule 12(b)(1) does “not strictly apply to motions based on the doctrine of primary jurisdiction.” *Sullivan v. Saint-Gobain Performance Plastics Corp.*, 226 F. Supp. 3d 288, 297 (D. Vt. 2016). However, “[d]espite its name, the doctrine is not jurisdictional,” and so an argument based on the doctrine of primary jurisdiction “is properly analyzed under Rule 12(b)(6).” *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 324-25 & n.11 (S.D.N.Y. 2017). Nonetheless, “the discussion [is] sufficiently akin to a motion under Rule 12(b)(1)—in connection with which matters outside the pleadings are properly considered— . . . so that consideration of documents beyond the four corners of the complaint is appropriate.” *Id.* at 325 n.11.

of her unjust enrichment claim (*see* Dkt. 15 at 11 n.1) and the Court accordingly grants this aspect of CVS Pharmacy’s motion. The Court considers the remaining arguments below.

D. Preemption

CVS Pharmacy argues that Plaintiff’s claims are preempted by the Public Readiness and Emergency Preparedness Act (“PREP Act”), 42 U.S.C. §§ 247d-6d, 247d-6e. (Dkt. 8-3 at 24). The PREP Act provides that:

[A] covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration [by the Secretary of Health and Human Services] has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(a)(1). The Secretary of Health and Human Services issued a declaration under the PREP Act regarding the COVID-19 pandemic in March of 2020. 85 Fed. Reg. 15198 (Mar. 17, 2020). Covered countermeasures under the PREP Act include: (1) “a qualified pandemic or epidemic product”; (2) security countermeasures, (3) drugs, biological products, or devices that are authorized for emergency use under the Food, Drug, and Cosmetic Act, and (4) certain respiratory protective devices. 42 U.S.C. § 247d-6d(i)(1). “[A] qualified pandemic or epidemic product” is defined as a drug, biological product, or device that is:

(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or

(II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 262 of this title;

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act.

Id. § 247d-6d(i)(7) (emphasis added). The PREP Act expressly preempts, “[d]uring the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration,” the enforcement of any state law “with respect to a covered countermeasure” that “(A) is different from, or is in conflict with, any requirement applicable under this section;” and “(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure[.]” *Id.* § 247d-6d(b)(8).

CVS Pharmacy’s briefing of its preemption argument is not a model of clarity. In particular, it is not entirely clear to the Court under what specific provisions of the PREP Act CVS Pharmacy is contending its hand sanitizer products qualify as “covered countermeasures.” It appears CVS Pharmacy may be arguing that CVS-brand hand

sanitizer is a qualified pandemic or epidemic product because it was used or manufactured to mitigate the COVID-19 pandemic, and because it was approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act via amendments made by the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”)—in other words, that the hand sanitizer satisfies the definition set forth in 42 U.S.C. § 247d-6d(i)(7)(A)(i)(I) and (B)(i). However, defense counsel was unable to confirm at oral argument that this was CVS Pharmacy’s position. The Court is hard-pressed to evaluate a legal argument that has not been articulated with any precision.

In any event, the Court cannot determine on the instant record whether Plaintiff purchased CVS-brand hand sanitizer prior to March of 2020, when the relevant declaration regarding the COVID-19 pandemic was issued and when the CARES Act was enacted. As the Court noted at oral argument, the date of Plaintiff’s purchase does not appear in the complaint. However, the proposed class extends to individuals whose hand sanitizer purchases were made not more than four years before the complaint was filed on May 18, 2022. (Dkt. 1 at ¶ 34). In other words, it is a plausible inference that Plaintiff purchased CVS-brand hand sanitizer in 2018 or 2019. Defense counsel conceded at oral argument that CVS Pharmacy’s preemption argument was based on the assumption that Plaintiff had purchased the hand sanitizer during the COVID-19 pandemic. At this stage of the proceedings, the Court cannot make that assumption, but must instead draw all inferences in Plaintiff’s favor, and assume that the hand sanitizer was not a covered countermeasure at the time of her purchase. Accordingly, the Court will not dismiss on the basis of preemption.

E. Primary Jurisdiction Doctrine

“The doctrine of primary jurisdiction is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties” and has a “central aim . . . to allocate initial decisionmaking responsibility between courts and agencies and to ensure that they do not work at cross-purposes.” *Ellis v. Trib. Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (quotations omitted). It “applies where a claim is originally cognizable in the courts, but enforcement of the claim requires, or is materially aided by, the resolution of threshold issues, usually of a factual nature, which are placed within the special competence of the administrative body.” *Golden Hill Paugussett Tribe of Indians v. Weicker*, 39 F.3d 51, 58-59 (2d Cir. 1994). In *Ellis*, the Second Circuit “highlighted four factors” that a court should consider in determining whether to apply the doctrine of primary jurisdiction:

(1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency’s particular field of expertise; (2) whether the question at issue is particularly within the agency’s discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made.

Palmer v. Amazon.com, Inc., 51 F.4th 491, 506 (2d Cir. 2022). However, “[n]o fixed formula exists for applying the doctrine of primary jurisdiction,” *Ellis*, 443 F.3d at 82 (citation omitted), and the analysis must be performed on a case-by-case basis, *Palmer*, 51 F.4th at 506. In addition to the *Ellis* factors, the Court “must also balance the advantages of applying the doctrine against the potential costs resulting from complications and delay in the administrative proceedings.” *Id.* (quotation omitted). “[O]nce a court determines

that the doctrine applies, it has discretion either: (1) to retain jurisdiction or (2) to dismiss the case without prejudice.” *Id.* at 505.

CVS Pharmacy’s argument that the doctrine of primary jurisdiction applies here is quite cursory. It asserts that “[t]he FDA clearly has the requisite expertise to regulate the labelling of hand sanitizers, as it already regulates extensively in the area as outlined [in connection with its preemption argument].” (Dkt. 8-3 at 27). CVS Pharmacy’s reply contains a more robust argument (Dkt. 19 at 14-16), but still fails to meaningfully address some of the *Ellis* factors. The Court is not persuaded that the doctrine of primary jurisdiction applies under the circumstances of this case.

As to the first *Ellis* factor, CVS Pharmacy’s argument turns on its contention that “Plaintiff’s case is premised on her claim that the [hand sanitizer] is allegedly ineffective (i.e., cannot kill “99.99%”—a more than 3 log reduction—of all known and unknown germs),” and that accordingly it is “the ‘science’ regarding the [hand sanitizers]’ germ killing efficacy and the FDA’s guidance under the TFM that validate and substantiate the label statements at issue, and it is that very science that is in dispute when Plaintiff claims that the label statements are ‘false’ and ‘misleading.’” (Dkt. 19 at 15). This is a misstatement of the core issue in this litigation. As CVS Pharmacy’s arguments on the merits make clear, it is not contending that its hand sanitizer products actually kill 99.99% of all known and unknown germs. (*See* Dkt. 8-3 at 16 (arguing that “no reasonable consumer would read the [hand sanitizer’s] front label claim to mean that hand sanitizer is intended killed [sic] 99.99% of all known and unknown germs”)). As such, the central dispute is not about what percentage of germs hand sanitizer can reliably kill—a question

that is arguably within the FDA’s purview—but is about how a reasonable consumer would interpret the phrase “kills 99.99% of germs” in this context. “The Court is well-equipped to answer this question.” *Elkind v. Revlon Consumer Prod. Corp.*, No. 14-CV-2484 JS AKT, 2015 WL 2344134, at *10 (E.D.N.Y. May 14, 2015) (collecting cases and finding that determination of whether the phrase “DNA advantage” as applied to cosmetics was misleading was a question of “consumer confusion rather than anything of the technical or scientific nature better suited to the FDA”); *see also In re Frito-Lay N. Am., Inc. All Nat. Litig.*, No. 12-MD-2413 RRM RLM, 2013 WL 4647512, at *8 (E.D.N.Y. Aug. 29, 2013) (finding that case involving the labeling of food products containing bioengineered products as “all-natural” was “far less about science than . . . about whether a label is misleading,” and that “the reasonable-consumer inquiry upon which some of the claims in this case depends is one to which courts are eminently well suited, even well versed” (quotation omitted)). The Court accordingly finds that the first *Ellis* factor weighs against application of the primary jurisdiction doctrine.

CVS Pharmacy has offered no meaningful argument as to the other *Ellis* factors, and the Court finds that they either weigh against application of the primary jurisdiction doctrine or are neutral. As to the second factor, as Plaintiff concedes, “regulating product statements for hand-sanitizer is conceivably within the FDA’s statutory discretion[.]” (Dkt. 16 at 23). However, “in the primary jurisdiction context, whether an agency is statutorily authorized to resolve a particular issue is not itself determinative of whether to apply the doctrine,” and “the question is not whether, in the abstract, it would be helpful for the agency to set standards of its own. The issue is instead whether the agency’s expertise

would materially assist the court in resolving difficult factual questions to determine whether specified legal standards have been violated.” *Palmer*, 51 F.4th at 508 (citation and alteration omitted). In this case, there are no factual disputes as to which the FDA’s expertise would materially aid the Court. As previously discussed, the central dispute is how a reasonable consumer would understand the phrase “kills 99.99% of germs,” and so the FDA’s input is “not required to resolve the pertinent factual issue before the Court[.]” *Id.* This factor thus does not favor application of the doctrine.

As to the third *Ellis* factor, the parties are in agreement that courts have already reached disparate results in similar cases. (See Dkt. 16 at 24; Dkt. 19 at 16). Accordingly, the danger of inconsistent rulings has apparently already been realized, and abstention in this one case would have little impact on the overall legal landscape. This is particularly true because, as discussed below in connection with the fourth factor, there is no pending application to the FDA that would resolve the issue. As such, the Court finds this factor neutral.

As to the fourth *Ellis* factor, there is nothing before the Court suggesting that any application has been made to the FDA to resolve the issue of whether a claim that alcohol-based hand sanitizer kills 99.99% of germs is misleading to a reasonable consumer. Plaintiff represents that she has not made such an application, and CVS Pharmacy does not claim to have done so. Counsel for both sides confirmed at oral argument that they were unaware of any such pending application. “Thus, awaiting FDA guidance on any issue relating to this action may mean waiting forever.” *GOJO Indus., Inc. v. Innovative Biodefense, Inc.*, 407 F. Supp. 3d 356, 363 (S.D.N.Y. 2019); see also *Palmer*, 51 F.4th at

511 (“Here, there is no pending proceeding before the agency, and there is no indication that the agency is poised to take up the specific questions before us, meaning that there is minimal, if any, concern that a court will resolve Plaintiffs’ claims and fashion a remedy in a way that would work at a ‘cross-purpose’ with [the agency’s] actions.”).

Finally, the Court has balanced the potential advantages and costs of applying the primary jurisdiction doctrine in this case, and finds that the latter outweigh the former. In the absence of any indication that the FDA intends to take up this issue, “abstention in favor of action by [the agency] has the potential to delay this litigation, without any likelihood of countervailing advantages.” *Palmer*, 51 F.4th at 511. Having considered all the circumstances of this action, the Court does not find that application of the doctrine of primary jurisdiction is warranted.

F. New York General Business Law Claims

Plaintiff alleges that CVS Pharmacy has violated §§ 349 and 350 of the New York General Business Law (the “GBL”). (Dkt. 1 at ¶¶ 42-68). As another court in this Circuit has recently explained:

Section 349 of the New York General Business Law declares unlawful “deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service.” Section 350 prohibits “false advertising in the conduct of any business, trade, or commerce or in the furnishing of any service.” Sections 349 and 350 are both aimed at conduct that is deceptive—*i.e.*, conduct likely to mislead a reasonable consumer acting reasonably under the circumstances. The only difference between the two is that Section 350 more narrowly targets deceptive or misleading advertisements, while Section 349 polices a wider range of business practices.

Colpitts, 527 F. Supp. 3d at 576 (quotations, citations, and alterations omitted).

“To state a claim for false advertising or deceptive business practices under New York . . . law, a plaintiff must plausibly allege that the deceptive conduct was likely to mislead a reasonable consumer acting reasonably under the circumstances.” *Mantikas v. Kellogg Co.*, 910 F.3d 633, 636 (2d Cir. 2018) (quotation omitted). It is “well settled that a court may determine as a matter of law that an allegedly deceptive advertisement would not have misled a reasonable consumer” under appropriate circumstances. *Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013).

The reasonable consumer inquiry is an objective one, and “in determining whether a reasonable consumer would have been misled by a particular advertisement, context is crucial.” *Id.* at 742. CVS Pharmacy argues that a reasonable consumer, viewing the statement “kills 99.99% of germs” in the context of a hand sanitizer label, would understand that it referred to “germs and bacteria commonly found on *hands*.” (Dkt. 8-3 at 18 (emphasis in original)). This argument has been accepted by several federal courts considering similar claims. *See, e.g., Robles v. Gojo Indus., Inc.*, No. SACV21928JVSDFMX, 2022 WL 2163846, at *6 (C.D. Cal. Mar. 16, 2022) (“[The plaintiff] was purchasing a product that was explicitly intended for use on the hands. In this context, it would not be reasonable to expect that she was purchasing a product that would kill germs that are transmitted through other means, or germs that are not yet known to science.”); *Souter v. Edgewell Pers. Care Co.*, No. 20-CV-1486 TWR (BLM), 2022 WL 485000, at *8 (S.D. Cal. Feb. 16, 2022) (“The Court accepts as true that [the defendant’s hand wipe products’ are ineffective against the diseases listed in Plaintiff’s First Amended Complaint and that, taken together, these disease-causing microorganisms comprise more

than 0.01 percent of germs. Based on the representations made on front and back labels for [the hand wipe products], however, the Court finds that a reasonable consumer would necessarily assume that the product kills 99.99% of germs that are transmissible by hand.”); *Piescik v. CVS Pharmacy, Inc.*, 576 F. Supp. 3d 1125, 1133 (S.D. Fla. 2021) (holding that “reasonable consumers would not, upon reading a hand sanitizer label that states the product ‘kills 99.99% of germs assume that this means it kills 99.99% of all conceivable disease-causing microorganisms, regardless of whether they are commonly found on the hands”); *but see Mier v. CVS Pharmacy, Inc.*, No. SACV2001979DOCADS, 2021 WL 1559367, at *5 (C.D. Cal. Mar. 22, 2021) (finding that the issue of “a consumer’s potential confusion that the [hand sanitizer] Product kills 99.99% of germs is a question of fact not appropriate for the pleadings stage”).

This Court agrees with the majority view that a reasonable consumer of hand sanitizer products would not understand the phrase “kills 99.99% of germs” to mean all germs in the universe, known or unknown, and regardless of whether such germs are found on the hands. As the *Piescik* court explained, “hand sanitizer is called *hand* sanitizer for a reason. . . . It defies all logic to assume that a reasonable consumer who purchases hand sanitizer will also expect it to offer protection against illnesses most commonly spread by drinking contaminated water, sexual contact, or by taking high doses of antibiotics in a healthcare setting.” 576 F. Supp. 3d at 1133 (quotation and alteration omitted and emphasis in original). While Plaintiff argues that “it is established that alcohol does not kill many types of known germs, including unenveloped viruses, bacterial spores, and the oocysts of protozoan parasites” (Dkt. 16 at 13), she does not argue and has not alleged that these types

of germs are commonly found on hands, such that a reasonable consumer would expect hand sanitizer to kill them.

A reasonable consumer would further be informed by the information contained on the hand sanitizer's rear label that the phrase "kills 99.99% of germs" does not refer to all germs, known and unknown. In particular, the qualification that the statement refers only to "many common germs that may cause illness" makes clear that the claim is limited to a subset of germs. Plaintiff argues that "[a] disclaimer on the side or back of a product cannot render a plaintiff's allegations of misleadingness implausible," citing *Mantikas*. (Dkt. 16 at 14). However, *Mantikas* was concerned with a circumstance where an ingredient list in "small print" on the side of the box was being relied on to "correct misleading information set forth in large bold type on the front of the box." 910 F.3d at 637. Here, there is no conflict between the statement on the front of the bottle and the additional information provided on the back; instead, "[t]he label at issue here is consistent with other cases where the back label was found to elaborate on, but not contradict, the representations on the front label." *Robles*, 2022 WL 2163846, at *6; *see also Beers v. Mars Wrigley Confectionery US, LLC*, No. 21-CV-2 (CS), 2022 WL 493555, at *5 (S.D.N.Y. Feb. 17, 2022) (explaining that *Mantikas* does not apply where "the Product's front label is not misleading." (citation omitted)).

At oral argument, Plaintiff's counsel argued that the claim, in fact, was that Plaintiff understood the hand sanitizer products at issue to kill 99.99% of germs commonly found on the hands, and that the information regarding specific types of germs and the number of germs in the universe was provided in order to show that the statement on the label was

literally false. This argument is unpersuasive. “[A] district court evaluating whether an advertisement is literally false must analyze the message conveyed in full context[.]” *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007).² Thus, contrary to Plaintiff’s apparent argument that the statement “kills 99.99% of germs” is literally false as a legal matter if alcohol-based hand sanitizer cannot kill 99.99% of all germs in the universe, whether known or unknown, an assessment of literal falsity is not made in this kind of context-free vacuum. Instead, the relevant question is whether Plaintiff has plausibly alleged that the statement “kills 99.99% of germs” as displayed on a bottle of hand sanitizer is literally false. For the reasons already set forth above, in context, this phrase would only be literally false if the product does not kill 99.99% of germs commonly found on the hands.

Further, the Court is not persuaded that Plaintiff has alleged that the hand sanitizer product she purchased does not kill 99.99% of germs commonly found on the hands. While Plaintiff’s counsel stressed at oral argument that the complaint contains many references to the hands and to hand sanitizer, the complaint is clear that the alleged falsity is that the hand sanitizer does not kill 99.99% of all germs. (*See, e.g.*, Dkt. 1 at ¶¶ 44-46, 57-59 (describing, among other things, the “promise made on the front of the bottle . . . that the

² While *Time Warner Cable* was decided in the context of a false advertising claim under § 43(a) of the Lanham Act, it is well-established that “[i]n terms of assessing whether a particular act was deceptive, ‘the standards for bringing a claim under § 43(a) of the Lanham Act are substantially the same as those applied to claims brought under the New York common law for unfair competition and §§ 349 and 350 of the New York General Business Law.’” *Express Gold Cash, Inc. v. Beyond 79, LLC*, No. 1:18-CV-00837 EAW, 2020 WL 9848431, at *3 (W.D.N.Y. Dec. 15, 2020) (original alteration omitted and quoting *Davis v. Avvo, Inc.*, 345 F. Supp. 3d 534, 540 (S.D.N.Y. 2018)).

hand sanitizer would kill 99.99% of all germs”)). Nowhere in the complaint as currently pled is there a factual allegation that CVS-brand hand sanitizer products do not kill 99.99% of germs commonly found on the hands. And while Plaintiff’s counsel indicated at oral argument that Plaintiff had an expert prepared to testify that the hand sanitizer product kills only 72% of germs commonly found on the hands, an attorney’s argument is not a substitute for a plausible factual allegation.

In sum, Plaintiff has not plausibly alleged that an objectively reasonable consumer would likely be misled by the label of CVS Pharmacy’s hand sanitizer products. Accordingly, her claims under the GBL are subject to dismissal.

G. Fraud Claim

Plaintiff has asserted a claim for common law fraud. (Dkt. 1 at ¶¶ 69-79). Federal Rule of Civil Procedure 9(b) provides: “In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). To state a claim for common law fraud under New York law, a plaintiff must allege: “(1) a material representation or omission of fact; (2) made with knowledge of its falsity; (3) with an intent to defraud; and (4) reasonable reliance on the part of the plaintiff, (5) that causes damage to the plaintiff.” *Haggerty v. Ciarelli & Dempsey*, 374 F. App’x 92, 94 (2d Cir. 2010). “[C]ommon law fraud claims are subject to the particularity requirements of Rule 9(b).” *Filler v. Hanvit Bank*, 156 F. App’x 413, 416 (2d Cir. 2005). “To satisfy the pleading standard for a misleading statement or omission under Rule 9(b), a complaint must ‘(1) specify the statements that the plaintiff contends were fraudulent, (2)

identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Employees’ Ret. Sys. of Gov’t of the Virgin Islands v. Blanford*, 794 F.3d 297, 305 (2d Cir. 2015) (citation omitted).

CVS Pharmacy argues that Plaintiff has failed to meet the Rule 9(b) standard “because she never says what benefit she expected from the [hand sanitizer] Product that she did not receive.” (Dkt. 8-3 at 20). Plaintiff argues in opposition that she has “adequately pled that the statement [regarding the hand sanitizer’s germ-killing capability] is literally false, giving rise to the belief that the product has been proven to be more effective than it actually is according to the current state of knowledge, and has been tested in a manner it has not been tested.” (Dkt. 16 at 16).

The Court agrees with CVS Pharmacy that Plaintiff’s allegations are insufficient to meet the Rule 9(b) standard. As noted above, to state a common law fraud claim in New York, a plaintiff must allege that there has been a false misrepresentation of a material fact, as well as reasonable reliance thereon. For all the reasons previously discussed, Plaintiff has not plausibly alleged that her reliance on her interpretation of the statement “kills 99.99% of germs” to mean all germs, regardless of whether they are commonly found on hands, was reasonable. Her fraud claim thus fails for essentially the same reasons as her GBL claims to the extent it is premised on the statement that the hand sanitizer kills 99.99% of germs. *See, e.g., Daniel v. Mondelez Int’l, Inc.*, 287 F. Supp. 3d 177, 199 (E.D.N.Y. 2018) (“For essentially the same reasons discussed regarding the material representation prong for the statutory claims, Plaintiff fails to plead reasonable reliance.”); *Bautista v. CytoSport, Inc.*, 223 F. Supp. 3d 182, 192 (S.D.N.Y. 2016) (“But, for the same reasons that

the § 349 claim fails, the fraud claim fails[.]”). And, as CVS Pharmacy correctly argues, Plaintiff has not identified any other benefit from the hand sanitizer that she expected to receive and did not. Accordingly, Plaintiff’s common law fraud claim is also subject to dismissal.³

H. Leave to Amend

In its opposition to CVS Pharmacy’s motion to dismiss, Plaintiff states: “Should the Court grant [CVS Pharmacy’s] motion as to any issue or claim other than those related to unjust enrichment, Plaintiff respectfully requests leave to amend.” (Dkt. 16 at 35). This “is not a proper motion for leave to amend, and fails to comply with the Local Rules of Civil Procedure with respect to the process for seeking to amend a pleading.” *Wi3, Inc. v. Actiontec Elecs., Inc.*, 71 F. Supp. 3d 358, 363 (W.D.N.Y. 2014) (explaining that, among other things, this District’s Local Rules require the party seeking to amend a pleading to “identify the proposed amendments through the use of a word processing red-line function or other similar markings” (quotations omitted)). The Court would accordingly be within its discretion to simply outright deny this “cursory or boilerplate request[.] . . ., made solely in a memorandum in opposition to a motion to dismiss.” *Malin v. XL Capital, Ltd.*, 312 F. App’x 400, 402 (2d Cir. 2009).

However, the Court cannot, on the record before it, rule out the possibility that Plaintiff could successfully plead some of her claims. *See Moreno*, 2022 WL 17668457,

³ CVS Pharmacy argued in its motion papers that Plaintiff’s fraud claim was barred by the economic loss doctrine. (Dkt. 8-3 at 31-32). CVS Pharmacy did not include that argument in its reply and defense counsel conceded at oral argument that it had been abandoned.

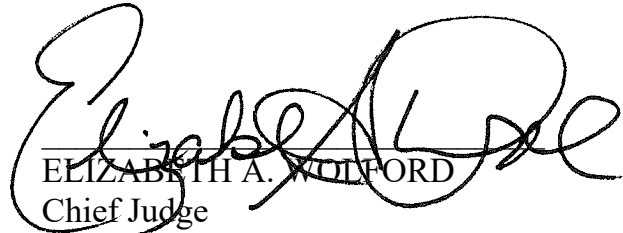
at *1 (vacating dismissal under Rule 12(b)(6) because the complaint could potentially “be amended to refer to germs commonly found on hands,” which would change the analysis). Indeed, defense counsel conceded at oral argument that the analysis in this case would be different if Plaintiff alleged that the hand sanitizer did not kill 99.99% of germs commonly found on the hands. Accordingly, the Court will conditionally grant Plaintiff’s request for leave to amend her non-unjust enrichment claims against CVS Pharmacy only, contingent on Plaintiff filing a motion that comports with the requirements of the Local Rules of Civil Procedure and that includes a viable proposed amended complaint, within 30 days of entry of this Decision and Order as set forth below.

CONCLUSION

For the foregoing reasons, the Court grants Defendants’ motions to dismiss. (Dkt. 7; Dkt. 8). Plaintiff’s claims against CVS Health Corp. are dismissed with prejudice and the Clerk of Court is directed to terminate it as a defendant. Plaintiff’s unjust enrichment claim is dismissed with prejudice.

The Court further conditionally grants Plaintiff’s request for leave to file an amended complaint as to her non-unjust enrichment claims against CVS Pharmacy, contingent on the filing by Plaintiff of a procedurally proper motion for leave to amend that includes a viable proposed amended complaint, within 30 days of entry of this Decision and Order. In the event such a motion is filed, the Court will enter a briefing schedule thereon. If no such motion is filed, the remaining claims against CVS Pharmacy shall be dismissed with prejudice, except that Plaintiff’s request for injunctive relief shall be dismissed without prejudice for lack of standing.

SO ORDERED.



ELIZABETH A. WOLFORD
Chief Judge
United States District Court

Dated: February 16, 2023
Rochester, New York